

CLAIMS

1. Particles for use as a carrier in the preparation of pharmaceutical formulations for the pulmonary
5 administration of micronized drugs by means of a powder inhaler, wherein the median diameter is greater than 90 μm and the surface rugosity is less or equal to 1.1.
2. Particles according to Claim 1, consisting of one or
10 more saccharides selected from glucose, mannose, galactose, sorbitol, mannitol, lactose, saccharose, trehalose, raffinose and cyclodextrins.
3. Particles according to Claims 1 and 2, consisting of α -lactose monohydrate.
- 15 4. Particles according to the preceding claims with a starting diameter between 30 and 600 μm .
5. Particles for use as a carrier according to claim 1, wherein the surface is coated with an additive selected from lubricants, anti-adherents and soluble polymers.
- 20 6. Particles according to Claim 5 in which the lubricant is magnesium stearate, sodium benzoate, or sodium stearyl fumarate.
7. Particles according to Claim 5 in which the anti-adherent is leucine or isoleucine.
- 25 8. Particles according to Claim 5 in which the soluble polymer is hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, polyvinylpyrrolidone, polyethylene glycol, or cyclodextrins.

9. A method of preparation of smooth carrier particles wherein smoothing of the particles is accomplished after repeated stages of wetting with a solvent and drying.

10. A method according to Claim 9, carried out using a high-speed granulator consisting of a cylindrical mixing chamber (container) in which a rotating paddle (impeller) and a spray nozzle are inserted, capable of operating in controlled conditions of temperature and pressure.

11. A method according to Claims 9 and 10, wherein the mixing time is between 120 and 300 minutes.

12. A method according to Claims 9-11 wherein a carrier substantially free from fine particles is obtained.

13. A method according to Claims 9-12, wherein the solvent used for smoothing contains, dissolved or dispersed, an additive in an amount between 0.05 and 2%.

14. A method for the preparation of pharmaceutical formulations wherein one or more active ingredients whose particles have a median diameter $\leq 6.4 \mu\text{m}$ are added to the carrier, prepared according to any one of the preceding claims.

15. A method according to Claim 14, wherein the active ingredient is a β -agonist.

16. A method according to Claim 15, wherein the active ingredient is salbutamol, formoterol, salmeterol, terbutaline, their salts and their epimers.

17. A method according to Claim 14, wherein the active ingredient is an anti-inflammatory steroid.

18. A method according to Claim 17, wherein the active

ingredient is beclometasone dipropionate, flunisolide, budesonide and their epimers.

19. A method according to Claim 14, wherein the active ingredient is an anticholinergic.

5 20. A method according to Claim 19, wherein the active ingredient is ipratropium bromide or oxitropium bromide.

21. Pharmaceutical compositions for inhalation, obtained by mixing active principles in the form of micronized powder with the particles of Claims 1-8.